

## **REMARKS**

### **FORMAL MATTERS:**

Claims 40 and 42-46 are now pending in this application.

Claims 1-39 and 41 have been canceled.

Claim 40 has been amended to more particularly point out and distinctly claim the invention.

The limitation relating to administering the formulation by inhalation was contained within previously pending now canceled claim 41.

In that claim 40 has been amended to refer to administering the formulation by inhalation this language has been deleted from dependent claims 45 and 46.

No new matter is added.

### **FORMAL MATTERS**

Applicant gratefully acknowledges the Examiner's acknowledgement of the acceptance of the substitute specification as well as acknowledgement of receipt of the application and payment of the necessary fees.

### **REJECTIONS UNDER §112, ¶1**

Claims 40-46 were rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement.

Summarizing, the essence of the rejection appears to be based on applicant's inclusion of the term "substance derived from." Without acquiescing to the validity of the rejection applicant has deleted this language from claim 40 thereby rendering the rejection moot.

### **REJECTIONS UNDER §103(A)**

Claims 40, 42 and 44 were rejected under 35 U.S.C. §103 as unpatentable over Grassme et al. in view of Albouz et al. The rejection is traversed as applied and as it might be applied to the presently pending claims. Without acquiescing to the validity of the rejection applicant has amended claim 40 to include the limitations contained within previously pending now canceled claim 41 relating to

inhalation. Claim 41 was not rejected over this combination of references. Accordingly, the rejection is believed to have been rendered moot.

**REJECTIONS UNDER §103(A) – CLAIM 43**

Claim 43 was rejected under 35 U.S.C. § 103 as unpatentable over Grassme et al. in view of Albouz et al. and further in view of Bilgi et al. The rejection is traversed as applied and as it might be applied to the presently pending claims.

Without acquiescing to the rejection applicant has amended claim 40 to include the limitations contained within previously pending now canceled claim 41 which was not rejected over this combination of references. Accordingly, the rejection is believed to have been rendered moot.

**REJECTIONS UNDER §103(A) – CLAIMS 41, 45 AND 46**

Claims 41, 45 and 46 were rejected under 35 U.S.C. § 103 as unpatentable over Grassme et al., in view of Albouz et al., and further in view of Bilgi et al. and further in view of Daines. The rejection is traversed as applied and as it might be applied to the presently pending claims.

Applicant claims a method of treating cystic fibrosis by administering an antidepressant by inhalation which is not taught in the prior art.

The primary reference to Grassme et al. has a publication date of March 2003. The present application is based on a PCT application which claims priority to German application 102 39 531 4 filed August 23, 2002. Thus, Grassme et al. is not prior art to the present application under 35 U.S.C. § 102.

Applicant has attached hereto the “Notice of Acceptance of Application under 35 U.S.C. § 371 and 37 C.F.R. § 1.495” and highlighted thereon is acknowledgement of receipt of the priority documents filed in the U.S. Patent and Trademark Office on February 18, 2005. Further, the Examiner’s Office Action of October 31, 2007 on page 2 acknowledges the foreign priority under 35 U.S.C. § 119 and specifically acknowledges copies of the certified copies of the priority documents as having been received. In view of such the primary reference to Grassme et al. is not prior art with respect to the present application. This, by itself, is sufficient to overcome all of the rejections. Accordingly, reconsideration and withdrawal on the rejections is respectfully requested.

The rejection relies also on Albouz et al. for its disclosure of using tricyclic antidepressants in decreasing ASM activity. However, nothing within the Albouz et al. publication suggests that such

tricyclic antidepressants could be used in treating infections/inflammation and specifically does not disclose the use of such in the treatment of cystic fibrosis.

The Bilgi et al. reference is also devoid of teachings regarding the use of drugs to prevent inflammation and infection.

The Daines patent has apparently been cited for its disclosure of administering drugs by inhalation. However, it does not disclose the administration of antidepressants or specifically tricyclic and tetracyclic antidepressants. Accordingly, even if Daines is combined with the other references it does not teach the presently claimed invention.

Notwithstanding all of the above it is applicant's position that it would not be obvious to combine the references in the manner suggested within the rejection. It is not realistic to pick and choose from any one reference only so much of it as supports a given position to the exclusion of other parts necessary to a full understanding of what that reference fairly suggests to one of ordinary skill in the art. Here the Grassme et al. publication is not prior art. However, even if were prior art combining it with the other references in the manner suggested within the rejection in order to teach towards a method of treating cystic fibrosis by administering tricyclic or tetracyclic antidepressants by inhalation would not be obvious. In view of such and in view of the other arguments provided above, reconsideration and withdrawal of the rejections and allowance of the application are respectfully requested.

## CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number AERX-134.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP



Date: 17 June 2009

By: \_\_\_\_\_  
Karl Bozicevic  
Registration No. 28,807

BOZICEVIC, FIELD & FRANCIS LLP  
1900 University Avenue, Suite 200  
East Palo Alto, California 94303  
Telephone: (650) 327-3400  
Facsimile: (650) 327-3231